

FDA Cervarix Briefing Document Errata

1. Page 3, in Product Formulation, change “fesacyl” to “desacyl”
2. Page 5, second paragraph, change “CBER consulted an outside rheumatologist” to “CBER consulted an outside neurologist”
3. Page 20, Table 14, delete the words, “and seronegative” from the table title
4. Page 20, Table 14, change case split for CIN2+ associated with HPV 45 from “0/5” to “0/4”
5. Page 20, Table 15, delete words “and seronegative in” from table title
6. Pages 57 and 58, Attachment 3, Tables 4 and 5, delete words, "and all specimens (combined cervical and cervicovaginal specimens)" from table title
7. Pages 57 and 58, Attachment 3, Tables 4 and 5, delete reference to “p-value” and how calculated from table footnote